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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,318	09/26/2003	Robert G. Rani	N-32720A/USN	8415
1095	7590	12/04/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080				NICOLAS, FREDERICK C
			ART UNIT	PAPER NUMBER
			3754	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/672,318	RANI, ROBERT G.	
	<b>Examiner</b> Frederick C. Nicolas	<b>Art Unit</b> 3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 02 November 2006.
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 2-9, 11-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 2-9, 11-19 and 21-23 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: Attached Drawings.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-4,8,11-14,18-19,21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin et al. 4,523,691.

Larkin et al. disclose a closure device for a flexible container containing a medical fluid (col. 1, ll. 5-11), which comprises a boat-shaped base section (19) having a top wall (15), a bottom wall, the base section adapted, to fit the flexible container as seen in Figure 6, a mid-section (14) connected to the top wall, a support (21) with a wing (22) connected to the mid-section, a cylindrical member (11) extending through the base section, the mid-section and the support as seen in Figure 4, the cylindrical member having a first opening in the base section and a second opening in the support

as seen in Figure 4, the cylindrical member adapted to allow the medical fluid to flow therethrough and exit the flexible container (col. 3, ll. 50-68 onto col. 4, ll. 1-2), a first seal (38) blocking the cylindrical member and capable of being breached, and a second seal (17) covering second opening and capable of being defeated, wherein a portion of the cylindrical member between the first seal and the second seal defines a chamber as seen in Figures 3-4, the first seal comprises a weakened section (35), a spike set (39), the base sealingly attached to an edge of the container as seen in Figure 7, the support further comprises a raised surface (see attached Figure 8 for location), at least one spacer (see Figure 3 for the location of one spacer), the at least one spacer comprises first and second wall members as seen in Figure 3, please note that the enclosure of the spacer forms the walls as seen in Figure 3.

Note: the applicant is advised that any action following the words "adapted for" and/or "capable of" in the claims indicates an intended use for the product and does not limit the structure of the product in the claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin et al. 4,523,691 in view of Babson 4,559,052.

Larkin et al. have taught all the features of the claimed invention except that the second seal is a peelable foil. Babson teaches the use of a second seal (3) being a peelable foil (col. 2, ll. 49-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the second seal of Larkin et al. to be made of peelable foil as taught by Babson in (col. 2, ll. 49-58), in order provide a seal that is impervious to air.

6. Claims 6-7,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin et al. 4,523,691.

Larkin et al. have taught all the features of the claimed invention except that the cylindrical member has a diameter from about 0.5 mm to about 12 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cylindrical member of Larkin et al. to have a diameter from about 0.5 mm to about 12 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

7. Claims 9,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin et al. 4,523,691 in view of Fowles 4,836,397.

Larkin et al. have taught all the features of the claimed invention except that the chamber is sterile after the closure device has experienced a sterilization process. Fowles teaches the use of a closure (10,12) being sterile after the closure has experienced a sterilization process (col. 4, ll. 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Fowles' teaching onto the closure device of Larkin et al., in order to allow the container and its contents to be in a sterile sealed environment.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ravn 3,071,274, Bujan 4,187,893, Karas et al. 5,540,674, Caspary et al. 6,179,821, McPhee 4,592,092, Miller et al. 5,125,919 and Duschek 5,125,921 disclose other types of closure device.

***Response to Arguments***

9. Applicant's arguments filed 11/2/2006 have been fully considered but are moot in view of the new ground(s) of rejection.

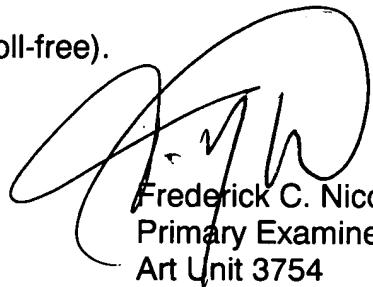
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (571)-272-4931. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver, can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

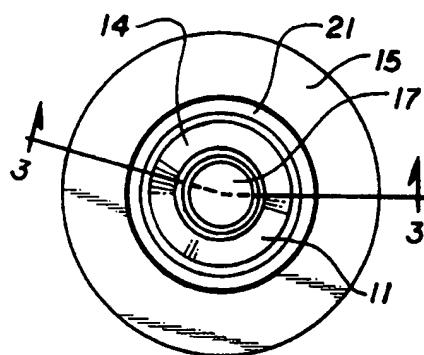
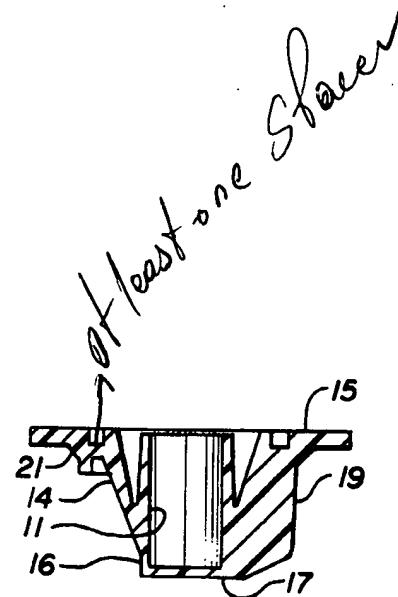
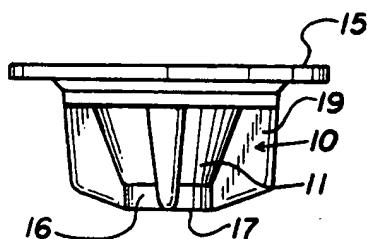
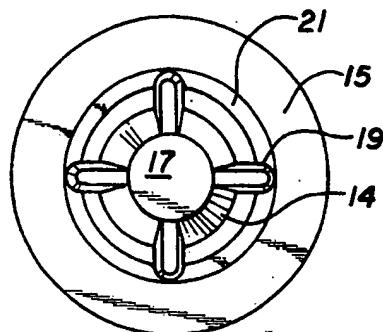
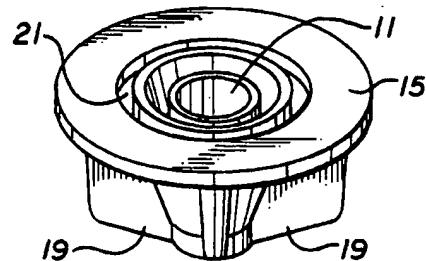
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FN  
November 22, 2006



11/22/06

Frederick C. Nicolas  
Primary Examiner  
Art Unit 3754

FIG. 2FIG. 3FIG. 1FIG. 5FIG. 4

